# A MULTI-COUNTRY COMPARISON OF INFORMATION AND DATA REQUIREMENTS FOR THE ENVIRONMENTAL RISK ASSESSMENT OF GENETICALLY ENGINEERED PLANTS

UNEP/GEF supported Phase II
Capacity Building Project on Biosafety

Ministry of Environment, Forest and Climate Change
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**Prepared by**

Ministry of Environment, Forest and Climate Change (MoEF&CC) in association with Centre for Environmental Risk Assessment-ILSI Research Foundation, Washington, USA under UNEP/GEF supported Phase II Capacity Building Project on Biosafety

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Developing Guidance for the Environmental
Risk Assessment of GE Plants

# A MULTI-COUNTRY COMPARISON OF INFORMATION AND DATA REQUIREMENTS FOR THE ENVIRONMENTAL RISK ASSESSMENT OF GENETICALLY ENGINEERED PLANTS

## 1 Introduction

The purpose of this report is to provide the Expart Committee for Preparation of Guidelines for Environmental Safety Assessment of Genetically Engineered Crops with a comparison of the information and data requirements for environmental risk assessment of genetically engineered (GE) plants in a selection of countries (or regions in the case of the European Union) with mature biosafety regulatory systems: Australia, Argentina, Brazil, Canada, the European Union (EU) and the United States (US). These five countries plus the EU include four of the top five producers of GE crops by hectare in 2010: US (66.8 million hectares), Brazil (25.4 M ha), Argentina (22.9 M ha) and Canada (8.8M ha); India was the fourth largest grower in 2010 with 9.4 million hectares of GE cotton[1]. The inter-country comparison is presented in section 2 of this report. Details about each country's specific regulatory regime for the environmental risk assessment of GE plants are found in Annex I.

Specific information and data requirements for molecular characterization are excluded from this report, as are considerations for the environmental risk assessment of applications for confined field trial permits. In India, guidance on the former has already been published in *Guidelines for the Safety Assessment of Foods Derived from GE Plants* and guidance on the latter in the *Guidelines and Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated GE Plants.*

For the sake of completeness, Annex II provides information about two intergovernmental organisations where the environmental risk assessment of GE plants is currently being discussed: 1. The *Ad Hoc* Technical Expert Group on Risk Assessment and Risk Management under the Cartagena Protocol on Biosafety; and 2. The Working Group on Harmonization of Regulatory Oversight in Biotechnology, under the Organization for Economic Cooperation and Development. In both cases, these groups seek to provide internationally accepted guidance on issues of relevance to environmental risk assessment.

## 2 Comparison of Environmental Risk Assessment Criteria

The purpose of environmental risk assessment of GE plants is to identify and evaluate the risks associated with the release and cultivation of these

[1] James, C. (2010). Global Status of Commercialized Biotech/GM Crops: 2010. ISAAA Brief 42-2010. International Service for the Acquisition of Agri-Biotech Applications (ISAAA), Ithaca, Ne w York.

plants in comparison with a conventional counterpart that has a history of safe use. Amongst those countries with established regulatory programs for environmental risk assessment of GE plants, there are commonly envisaged sources of potential harm that are addressed on a case-by-case basis prior to commercialization of the plant:

- The GE plant may become a weed of agriculture or may be invasive in natural habitats;
- Gene flow from the GE plant to wild relatives may produce weedy or invasive hybrids;
- The GE plant may have adverse environmental impacts on secondary and non-target species;
- The GE plant may have an adverse impact on biodiversity.

In order to facilitate the inter-country comparison reported here, information and data requirements to address these potential harms have been categorized under the following headings:

1 Description of the biology of the plant species prior to modification
2 Phenotype of the GE plant
3 Cultivation of the GE plant
4 Impact of outcrossing with sexually compatible relatives
5 Impact on Non Target Organisms
6 Other adverse impacts on biodiversity

This section presents a comparison of the specific information requirements related to premarket environmental risk assessment that have been published by regulatory authorities in Argentina, Australia, Brazil, Canada, the EU and the US. In 2001, Canada and the US harmonized information requirements for the environmental risk assessment of GE plants[2]. The risk assessment criteria from the resulting bilateral agreement have been used where appropriate *in lieu* of separate requirements for each country.

In the following tables, a check mark (√) indicates that the information or data requirement is included within the regulatory or guidance documents published by that competent authority, or has been substantiated through personal communications with a regulatory official.

An "I" indicates that while the information or data requirement listed may not be explicitly identified within regulations or guidelines, it may be a parameter that is encompassed within a broader category of information/data that is required by regulatory authorities. For example, the number of days to onset

[2] CFIA. (2001). Canada and United States Bilateral Agreement on Agricultural Biotechnology: Appendix II: Environmental Characterization Data for Transgenic Plants Intended for Unconfined Release. Canadian Food Inspection Agency (CFIA), Ottawa. http://www.collectionscanada.gc.ca/webarchives/20071123101541/http://www.inspection.gc.ca/english/plaveg/bio/usda/appenannex2e.shtml

of flowering, number of days for flowering and number of days until maturity may be used as indicators of rate of reproduction.

Most functioning regulatory systems provide flexibility to deal with product specific variations and hence certain data are not obligatory in every situation. To the extent possible, these case-by-case optional requirements have been indicated by an "O".

Where no reference to a specific data requirement is made in the regulations, and no information was provided by personal communication with a regulatory official, the space has been left blank.

## 2.1 Description of the Biology of the Non-transformed Plant Species

In order to assess the safety of a GE plant or derived product, one must be familiar with the biology of the plant itself, as well as the agricultural practices employed in its cultivation and its uses in livestock feed and food. This concept of familiarity is a key approach used in identifying and evaluating potential risks and also in informing management practices that may be needed to mitigate recognized risks.

One of the most useful reference tools when conducting an environmental risk assessment of a transgenic plant is a detailed monograph describing the biology of the species under review. Specifically, it can be used to identify species-specific characteristics that may be affected by the novel trait so as to permit the transgenic plant to become "weedy", invasive of natural habitats, or be otherwise harmful to the environment. It can also provide details on significant interactions between the plant and other life-forms that must be evaluated in the impact analysis.

Detailed consensus documents describing the biology of a number of crop species have been prepared by the Organisation for Economic Cooperation and Development (OECD)[3]. These biology documents can be used both as credible sources of information about the species reviewed, and as templates for the preparation of new monographs. It is important, however, to note that much of the value of biology documents lies in the country-specific information provided about the plant species. Consensus documents like those published by the OECD must be supplemented to reflect national conditions as has been done by India[4], Canada[5] and Australia[6]. The OECD has published a useful resource to this end entitled "Points to Consider for Consensus Documents on the Biology of Cultivated Plants[7]".

[3] OECD's consensus documents on the biology of crops can be found at http://www.oecd.org/document/15/0,3746,en_2649_34385_46726799_1_1_1_1,00.html.

[4] Documents on the biology of cotton, maize, okra and rice can be found at http://igmoris.nic.in/.

[5] Biology documents published by the Canadian Food Inspection Agency can be found at http://www.inspection.gc.ca/english/plaveg/bio/dir/biodoce.shtml.

[6] Biology documents published by the Office of the Gene Technology Regulator can be found at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/riskassessments-1.

[7] http://www.oecd.org/LongAbstract/0,3425,en_2649_34385_36397740_1_1_1_1,00.html

| Information/Data Requirement | Argentina | Australia | Brazil | Canada-US Bilateral | EU |
|---|---|---|---|---|---|
| Common or usual names; scientific name and taxonomic classification | √ | √ | √ | √ | √ |
| General biology/agronomy/ecology of the plant species | √ | √ | √ | √ | √ |
| Centres of origin, genetic diversity and cultivation | √ | √ | √ | √ | I |
| Breeding and seed production practices | - | - | - | √ | √ |
| Agronomic practices | - | - | - | √ | - |
| Reproductive biology | √ | √ | √ | √ | √ |
| Weediness characteristics | √ | √ | I | √ | √ |
| Potential for intra- and inter-specific hybridization | √ | √ | √ | √ | √ |
| Occurrence of sexually compatible species | √ | √ | √ | √ | √ |
| Interactions with other life forms[1] | √ | √ | √ | √ | √ |
| History of use and/or distribution in the country proposed use | √ | √ | √ | √ | √ |

[1] *e.g.*, pollinators, mycorrhizal fungi, animal browsers, birds, soil microbes and soil insects.

## 2.2 Phenotype of the GE plant

GE plants are routinely evaluated for agronomic performance and phenotypic characteristics in comparison with a conventional counterpart. In addition to yield and performance data, other parameters may include seed dormancy and germination rates, time to flowering or maturity, plant height and vigour, time to pollen shed and susceptibility to disease. These data are used when evaluating potential environmental consequences of introduction, particularly in assessing any increased tendency to weediness, competitiveness or invasiveness.

Among the countries in this comparison, Canada, Australia and the US have been most explicit in publishing detailed information requirements for phenotypic characterization of the engineered plant. For the other countries, many of the same parameters may be inferred from general requirements to examine any changes in reproductive biology, pollen or seed dispersal, outcrossing and impacts on beneficial insects.

| Information/ Data Requirement | Argentina | Australia | Brazil | Canada-US Bilateral | EU |
|---|---|---|---|---|---|
| Growth habit[1] | √ | I | I | √ | √ |
| Life-span[2] | √ | I | I | √ | √ |
| Vegetative vigour[3] | √ | I | I | √ | √ |
| Ability to overwinter (or overseason) | √ | I | I | √ | √ |
| Number of days to onset of flowering; number of days | √ | I | I | √ | √ |
| for flowering | √ | I | I | √ | √ |
| Number of days until maturity[4] | √ | I | I | √ | √ |
| Seed parameters[5] | √ | √ | I | √ | √ |
| Proportion surviving from seedling to reproduction | √ | I | I | √ | √ |
| Outcrossing frequency (intra- and interspecific)[6] | √ | √ | √ | √ | √ |

| | | | | | |
|---|---|---|---|---|---|
| Impact on pollinator species | √ | √ | √ | √ | √ |
| Pollen parameters[8] | - | √ | I | √ | √ |
| Fertility[9] | √ | I | I | √ | √ |
| Self-compatibility | - | I | I | √ | √ |
| Asexual reproduction[10] | √ | √ | √ | √ | √ |
| Seed dispersal factors[11] | √ | √ | √ | √ | √ |
| Symbionts[12] | | √ | √ | √ | √ |
| Stress adaptations[13] | √ | √ | √ | √ | √ |
| Add or subtracts substances to/from soil | - | √ | √ | - | - |

1 *e.g.*, basic morphology of the plant, including any abnormalities.

2 Annual, biennial or perennial and if this has changed from the non-transformed parental plant.

3 *e.g.*, plant height, crop biomass, etc.

4 e.g., time to the production of mature fruit or seed (suitable for harvesting).

5 *e.g.*, seed production; length of time (days) of seed/fruit production; seed dormancy: Characterize any changes in the ability of the seed to remain viable over time; seedling emergence.

6 Changes in outcrossing frequency are generally an inferred conclusion based on other empirical observations related to reproductive biology, and not on experimental measurements of gene flow for the engineered plant.

7 *e.g.*, changes in pollinator species visiting flowers and data on changes in flower morphology, colour, fragrance, etc. that may affect interactions with pollinators.

8 *e.g.,* amount of pollen produced, proportion of viable pollen; the longevity of pollen under varying environmental conditions; physical parameters such as stickiness, shape, and weight.

9 *e.g.,* fertility acquired or lost.

10 *e.g.,* vegetative reproduction; ability of the plant material to set roots; parthenocarpy.

11 *e.g.,* characteristics such as seed shattering or dispersal by animals.

12 *e.g.,* Vesicular-arbuscular mycorrhizal fungi, rhizobia.

13 To biotic and/or abiotic stresses, including changes in disease susceptibility.

## 2.3 Cultivation of the GE plant

Baseline information on the receiving environment, including knowledge of existing agricultural practices for the plant species (e.g., methods of pest and weed control, soil fumigation, crop rotation etc.), is used to evaluate the impact of the environmental introduction of the GE plant, or changes in agricultural practice. Information on any anticipated changes in agronomic practices as a result of the genetic modification may be particularly important in assessing the need for specific deployment strategies, risk mitigation measures, or product stewardship.

| Information/Data Requirement | Argentina | Australia | Brazil | Canada-US Bilateral | EU |
|---|---|---|---|---|---|
| Describe where the engineered plant will be grown | √ | √ | √ | √ | √ |
| Identify and describe any new ecosystems where the GE plant will be cultivated. | I | √ | √ | √ | √ |
| Describe changes in cultivation practices for the GE plant[1] | I | √ | √ | √ | √ |
| Discuss if transgenic volunteers may require altered management practices for succeeding crops | I | √ | I | √ | √ |
| Describe any specific deployment strategies recommended for this engineered plant[2] | I | √ | I | √ | √ |

| | | | | | |
|---|---|---|---|---|---|
| Insect resistance management plans | - | √ | √ | √ | √ |
| Herbicide resistant crop management[3] | - | I | I | √ | √ |

[1] Examples may include land preparation, fertilizer usage, weed and pest control, harvest, postharvest protocols, and other cultivation practices.

[2] Deployment strategies may include geographic or temporal factors, or integration with other practices.

[3] In the case of GE plants developed for tolerance to a herbicide or class of herbicides, describe appropriate strategies that are intended

## 2.4 Impact of Outcrossing with Sexually Compatible Relatives

The potential for introgression of genetic material from one plant to another is significant when certain conditions are met such as the two plants are naturally sexually compatible, in sufficiently close proximity for cross pollination to occur, and their hybrid offspring are viable (i.e., can become established and reproduce). In order to assess potential environmental risks associated with outcrossing from GE plants, the reproductive biology of the plant and distribution of sexually compatible relatives must be known, and the impact of the introduced trait, should it be introgressed into other plant species, should be considered. Dispersal and gene flow are not hazards *per se* and so the environmental significance of trait introgression requires trait x species assessment. The potential for outcrossing is a parameter that all countries in this comparison assess as part of the phenotypic characterization of the engineered plant, but not all countries stipulate specific requirements to evaluate the potential impacts of gene flow.

The possibility of horizontal gene transfer (HGT) from plants to microorganisms in the soil, particularly as this relates to the possible transfer of genes encoding antibiotic resistance, has been considered a potential hazard associated with GE plants. The potential for HGT from plants to microorganisms has been comprehensively studied and reviewed in both the literature and by many regulatory authorities. While it may remain as a criterion to be addressed in a risk assessment dossier in some countries, this is typically done by referencing the scientific literature and not through experimentation.

| Information / Data Requirement | Argentina | Australia | Brazil | Canada -US Bilateral | EU |
|---|---|---|---|---|---|
| Presence of sexually compatible species in areas where the crop will be cultivated[1] | √ | √ | √ | √ | √ |
| Characteristic(s) of introduced trait that could change the ability of the engineered plant to interbreed with other plant species | √ | √ | √ | √ | √ |
| Consequences of potential for gene flow from the engineered plant to sexually compatible species[2] | √ | √ | √ | √ | √ |
| Potential changes in likelihood of HGT to unrelated species | - | √ | √ | - | √ |

[1] Sexually compatible wild relative(s) should be characterized with respect to weediness in managed ecosystems, and/or establishment and spread in unmanaged ecosystems.

[2] Consider whether: the introduced trait is similar to a trait found currently in natural populations of the sexually compatible wild relatives; the introduced trait will have the potential to increase the reproductive fitness or confer a selective advantage on the wild relative; the introduced trait will have a significant impact on the establishment and spread of populations of wild relatives.

## 2.5 Impact on Non-Target Organisms

Information on the nature of the introduced trait is used to determine the likelihood of nontarget effects, and, if indicated, the range of non-target organisms that are appropriate for ecotoxicity testing. Generally, the range of test species selected includes the following functional groups found in agricultural fields and other habitats: birds, freshwater fish, predators and parasitoids of crop pests, soil invertebrates and pollinators. If detrimental effects are observed under laboratory conditions, field studies are required to assess the actual abundance of non-target species under test and control conditions.

Among the countries in this comparison, there is broad similarity on the requirement for information on non-target organisms.

| Information/Data Requirement | Argentina | Australia | Brazil | Canada-US Bilateral | EU |
|---|---|---|---|---|---|
| Has gene product been part of the human or animal diet | √ | √ | √ | √ | √ |
| Gene product known to lead directly or indirectly to expression of a toxin or other product that is known to affect metabolism, growth, development, or reproduction of animals, plants, or microorganisms | √ | √ | √ | √ | √ |
| Potential physiological and behavioural effects to nontarget organisms | √ | √ | √ | √ | √ |
| Potential adverse effects on the health of humans[1] | √ | √ | √ | √ | √ |

[1] Adverse affects to workers, adults, and children that may arise through physical contact with or use of the engineered plant or its parts or its raw or processed products, when used for other than food, feed, or pharmaceuticals. The analysis might include a comparison of the engineered and non-engineered counterpart(s) with respect to the likely exposure to toxins, irritants, and allergens.

## 2.6 Other Environmental Considerations

Canada and the US are the only countries to ask for additional information for GE plants developed using plant viral coding regions. In such cases, synergy, facilitated movement, transcapsidation, and viral recombination are to be addressed[8], which is typically achieved using information from the peer-reviewed literature.

# 3. Other Regulatory Considerations

All of the countries reviewed for this comparison have other requirements that are not safety related *per se*, but instead may be best characterised as responses to policy considerations. The most significant of these are summarized below:

[8] Appendix II: Environmental Characterization Data for Transgenic Plants Intended for Unconfined Release of the Canada and United States Bilateral Agreement on Agricultural Biotechnology references the OECD consensus document Crop Plants Made Virus Resistant through Coat Protein Gene-Mediated Protection for terminology. It can be found at http://www.oecd.org/dataoecd/17/6/46815568.pdf.

## 3.1 Detection Requirements

Event specific detection methods are required by Argentina, Australia, Brazil, Canada and the EU. Canada and the EU have published guidance on acceptable methods for detection and performance criteria[9].

## 3.2 Post-Release Environmental Monitoring

Case-specific, hypothesis driven, post release environmental monitoring is required in Australia, Brazil, Canada, the EU and the US (by USEPA, but not APHIS). The most common example of this type of monitoring is that used to ensure the implementation of insect resistance management plans for crops expressing insecticidal proteins isolated from *Bacillus thuringiensis* (Bt)[10].

General surveillance of GE crops after authorization for unconfined release (i.e., non-hypothesis driven monitoring where causality cannot be determined) is explicitly required only in Brazil and the EU[11].

Importantly, Brazil recently modified its requirements for general surveillance monitoring when National Technical Committee on Biosafety (CTNBio) approved a new monitoring framework that provides for flexibility in ascribing monitoring requirements and allows for case-specific exemptions from the requirements for monitoring[12].

Legislation in Canada[13] and Australia[14] requires that the regulatory authority be notified of any new information that arises after the authorization for the unconfined release of a GE event is granted and that is pertinent to environmental and human health safety. In Australia, Risk Assessment and Risk Management Plans (RARMPs) are prepared by the Office of the Gene Technology Regulator (OGTR) for each application for a dealing involving an intentional release. RARMPs are reviewed by "prescribed experts, agencies and authorities"[15], and by interested members of the public. In the case of licences for releases without limits and controls (i.e., an unconfined release), the RARMP will include provisions for oversight measures for post release review on a case-by-case basis. In Canada, CFIA's guidance states that "a general post-release monitoring plan to monitor for unintended or unexpected environmental effects of an authorized product should also be an integral part of a complete application and will be reviewed during the environmental

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[9] For Canada, see: http://www.inspection.gc.ca/english/plaveg/bio/detecte.shtml. For the EU, see the guidance documents of the European Union Reference Laboratory for GM Food and Feed: http://gmocrl. jrc.ec.europa.eu/guidancedocs.htm.

[10] In Argentina, insect resistance management of Bt crops not legally required; it is a voluntary stewardship initiative developed by the Asociación Semilleros Argentinos, approved by CONABIA, and implemented by product developers.

[11] For Brazil, see http://www.ctnbio.gov.br/index.php/content/view/12857.html. For the EU, see: http://www.efsa.europa.eu/en/efsajournal/pub/2316.htm.

[12] Normative Resolution No. 5 initially required a monitoring period of five years for all approved GE events. A floe chart for the new monitoring scheme in Brazil can be found at www.mct.gov.br/index.php/content/view/334734.html.

[13] Seeds Regulations, Part V [14] Gene Technology Act, 2000

[15] http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/evalprocess-3/$FILE/DIRprocess.pdf

safety assessment of the novel plant in question. A stewardship plan may be considered acceptable for post-release monitoring purposes"[16]. Argentina has recently adopted a requirement similar to Canada's for the inclusion of a monitoring plan with an application for unconfined release[17]. The U.S. has no requirements for general surveillance although US Environmental Protection Agency (USEPA), through Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), requires immediate reporting of any evidence of adverse effects, including product failure or unexpected toxicity associated with Plant Incorporated Protectants (PIPs).

## 3.3 Treatment of Stacked Events

Approaches to dealing with intentional trait stacking (*i.e.*, conventional crossbreeding of two approved GE events to produce progeny expressing the combined "package" of novel traits) vary significantly among the countries in this comparison. Different countries have adopted entirely different approaches that range from having no requirement for additional regulatory oversight to treating stacked events as if they were entirely new GE events.

The United States has adopted a policy of "safe apart – safe together" such that if the individual GE parental lines have been determined to be as safe as their conventional counterparts, it is concluded, based on knowledge and experience from conventional breeding, that the breeding stack of individual events will also be safe. Thus, there is no specific regulation of stacked events, except in certain cases. The qualification is in the case of breeding stacks that combine two, or more, pesticidal traits (plant incorporated protectants), as these must undergo a separate registration process under the FIFRA administered by U.S. EPA.

While explicit authorization of stacked events is generally required in both Australia and Brazil, there is some flexibility in how these products may be treated. In Australia, the OGTR requires that every activity involving the environmental release of a GE organism, including stacked events, be conducted under a license.[18] This requirement may be met either through a separate license for the stacked event or through the inclusion of specific conditions within the licenses for the parental events to encompass stacking between the parental events. Requests for variances to allow stacking between separately licensed GE events are considered on a case-by-case basis by OGTR, which requires that sufficient data be available to assess if a particular stacked event poses risks which need specific treatment in the license conditions.

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[16] See section 7.6 in Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits. http://www.inspection.gc.ca/english/plaveg/bio/dir/dir9408e.shtml#ch7-6.

[17] The Secretary of Agriculture, Livestock and Fisheries passed Resolution 701/2011 in October 2011 which provides revised information and data requirements for the release of genetically engineered plants. It can be found (in Spanish) at http://www.cda.org.ar/index.php?option=comcontent&view=article&id=10469:resolucion- 7012011-biotecnologia-agropecuaria&catid=54&Itemid=90.

[18] Policy on licensing of plant GMOs in which different genetic modifications have been combined (or 'stacked') by conventional breeding. Available on the Internet at: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dirpolicy-3/$FILE/gmstacking08.pdf (last accessed 12 December 2011).

The regulation of stacked events by Brazil is dealt with under Article 4 of Normative Resolution No. 5, which provides the CTNBio with the discretion to waive the requirement for an assessment and technical opinion, on a case-by-case basis upon consultation, in situations where the parental events have been approved for commercial release in Brazil.[19]

Canada has taken an intermediate approach, whereby developers are asked to advise the Canadian Food Inspection Agency (CFIA) at least 60 days prior to the anticipated environmental release stacked events. In this case, stacking of traits with potential incompatible management requirements, possible negative synergistic effects, or where production of the plant may be extended to a new area of the country, may elicit the requirement for an environmental risk assessment of the stacked event. [20] To date, this requirement has not been triggered.

| Information Data/ Requirement | Argentina | Australia | Brazil | Canada | EU | US |
|---|---|---|---|---|---|---|
| Approval needed for stacked events | √ | √ | √ | O[1] | √ | O[2] |
| New environmental data required for stacked event product | O[3] | O[4] | O[5] | - | √[6] | |

1 The requirement for a risk assessment of stacked events is considered on a case-by-case basis by the CFIA, which requests a letter of notification 60-days prior to the environmental release of a stacked event.

2 Approval of stacked events is not a requirement of USDA-APHIS, but in cases where pesticidal traits are stacked, the USEPA requires registration of the new combined active ingredients.

3 CONABIA determines if additional information on the stack may be required on a case-by-case basis.

4 OGTR considers the presentation of new data on stacked events on a case-by-case basis.

5 CTNBio may waive the requirement for an assessment on a case-by-case basis and upon consultation.

6 EFSA guidance states that the risk assessment of a higher order stack i.e., multiple events combined in a single stack, can cover all combinations of fewer of these events. Field trial data from one representative growing season may be required for stacked events. See: http://www.efsa.europa.eu/en/efsajournal/doc/512.pdf.

19 CTNBio Resolução Normativa Nº 5, de 12 de março de 2008. Available on the Internet at:http://www.ctnbio.gov.br/index.php/content/ view/11444.html (last accessed 12 December 2011).

20 Directive 94-08: Assessment criteria for determining environmental safety of plants with novel traits. Available on the Internet at: http://www.inspection.gc.ca/english/plaveg/bio/dir/dir9408e.shtml#ch2-4 (last accessed 12 December 2011).

# 4. Summary

In all five countries and the EU, environmental risk assessment includes: the concept of familiarity; the application of a comparative approach; and the importance of case-by-case assessment. It should be noted that the latter does not mean that risk assessments should be undertaken in isolation, but that there should be a deliberate inclusion of information and experience gained through prior risk assessments, including risk assessments undertaken by other governments. The OGTR's Risk Analysis framework is instructive in that it provides clear guidance on how the Regulator evaluates the quality of evidence, including the consideration of assessments undertaken by regulators in other countries.

There is a high degree of harmonization across countries in terms of what information and data should be considered in the context of an environmental risk assessment. The information requirements and safety assessment criteria appear more detailed and explicit in countries with significant experience in reviewing applications for commercial cultivation of GE crops. In contrast, guidance is often more general and dependent on case-by- case determinations in countries with more limited experience. Post-release environmental monitoring is an evolving issue in all countries and the EU. While all governments require case-specific, hypothesis driven monitoring (*e.g.*, insect resistant management of *Bt* crops), there remains uncertainty about the value of general surveillance. The most informative example is that of Brazil, the only country in the world that has applied general surveillance monitoring to events that are cultivated on significant, commercial scale acreages. This experience has led the Brazilian regulatory authority, CTNBio, to revisit the approach initially described in Normative 5 and to provide more flexibility and the option of obtaining case-specific exemptions from the requirement for general surveillance monitoring.

# Annex I: Country Specific Information

## 1 Argentina

| Summary of regulatory system for unconfined (commercial) release for domestic cultivation in Argentina | |
|---|---|
| Regulatory Authority | Secretary of Agriculture, Livestock and Fisheries (SAGyP) under the Ministry of Agriculture, Livestock and Fisheries (MAGyP) |
| Law | |
| Regulations | MAGyP Nº 763; SAGyP N° 701/11; SENASA N° 412/02; SAGyP Nº 510 |
| Guidance | |

Approvals for the environmental release of genetically modified organisms (GMOs) are conducted under regulations administered by the Secretary of Agriculture, Livestock and Fisheries (SAGyP). In 1991, SAGyP created the Comision Nacional Asesora de Biotecnologia Agropecuaria (the National Advisory Committee on Agricultural Biosafety; CONABIA) under Resolution N° 124/91 as a mechanism to provide advice on the technical and safety requirements to be met for environmental releases, human food, and livestock feed uses of genetically engineered plant and animal materials. CONABIA's membership is composed of both public and private sector representatives with a wide range of expertise in agricultural biotechnology. Members are selected according to a transparent process (Disposition N° 004/00) and are approved by SAGyP.

The regulatory requirements for GMOs are found in guidelines in the form of non-legislative resolutions that are integrated into the overall regulatory system that governs the release of products in the agricultural sector. Although the system is not considered as voluntary, there is no specific law that makes the resolutions legally binding. Under this framework, specific guidelines have been developed to establish conditions under which environmental releases of transgenic materials may be conducted. Resolution MAGyP Nº 763 stipulates the three stages that must be completed for commercial release of a GE plant[21]:

- **Stage 1:** Assessment of the risk to the agroecosystem derived from growing the GM crop in question at large scale. This assessment is conducted by the Biotechnology Directorate of SAGyP and CONABIA in accordance with the recently published Resolution SAGyP N° 701/11.
- **Stage 2:** Assessment of the material as food or feed for human and/or animal consumption, which is carried out by the National Service of Agrifood Quality and Health (SENASA) and the National Advisory Committee on GMO Use (CTAUOGM), according to Resolution SENASA N° 412/02.
- **Stage 3:** Report on the productive and commercial impacts of the commercialization of the subject event, carried out by the Directorate of Agricultural Markets within the Ministry of Agriculture, Livestock and Fisheries, as stipulated in Resolution SAGyP Nº 510.

[21] http://www.minagri.gob.ar/site/agricultura/biotechnology/55-COMMERCIAL%20PERMITS/index.php

The first two opinions are event specific and apply to the event as well as any progeny derived from that event using conventional breeding techniques (i.e., all derived varieties are also approved when the event is approved). This third opinion is based on a direct economic, market-based review, completely separate from the safety assessments provided by the other two agencies and is one of the few examples in the world where non-safety issues are explicitly taken into account in the decision to approve or not approve a GE crop. This requirement reflects the economic importance of agricultural exports to Argentina's economy. The market focus of this assessment and the subsequent commercial opinion are different from the safety opinions which are based on scientific criteria.

## 2 Australia

| **Summary of regulatory system for unconfined (commercial) release for domestic cultivation in Australia** | |
|---|---|
| Regulatory Authority | Office of the Gene Technology Regulator (OGTR) |
| Law | *Gene Technology Act, 2000* |
| Regulations | Gene Technology Regulations, 2001 |
| Guidance | Risk Analysis Framework; Application for license for dealings with a GMO involving intentional release of the GMO into the environment (DIR) |

Australia's current regulatory framework was developed through extensive consultations with relevant government agencies, academic and private sector developers, consumer and environmental groups, primary producers, industry and the public. The end product was the *Gene Technology Act*, *2000* which received Royal Assent on 21 December 2000 and came into force in June 2001.

The provisions of *the Gene Technology Act, 2000* are "in addition to, and not in substitution for, the requirements of any other law of the Commonwealth (whether passed or made before or after the commencement of the Act)". An Inter-Governmental Agreement, between the Commonwealth and the States and Territories of Australia, provides the basis for complementary legislation to the Gene Technology Act, 2000 in their jurisdictions. The individual States and Territories in Australia regulate land use in their own jurisdictions and have in place legislation to allow the responsible minister to prohibit the planting of specific GE crops.

Under *the Gene Technology Act, 2000* approval or authorization must be obtained to deal with GMOs. Dealings include contained research as well as all field trials and cultivation in Australia and any field trial is considered to be a 'dealing involving intentional release or DIR'. Approval for commercial cultivation is handled as an intentional release under the same system as a field trial. To provide some guidance to the process of risk assessment and

the application process for approval of dealings with modified organisms, the OGTR publishes the Risk Analysis Framework[22] with detailed requirements on the information required. These information requirements have been developed into a detailed form to apply for a licence for a deliberate release into the environment (DIR)[23].

The *Gene Technology Act, 2000* mandates a broad consultation process before approval of GMOs for intentional release to the environment. If the initial assessment by the OGTR determines that the release may pose a 'significant risk to the health and safety of people or the environment', then there is a public consultation on the application. Otherwise an 'Early Bird' public notification is made and input is sought from prescribed expert groups and key stakeholders. A Risk Assessment and Risk Management Plan (RARMP) is prepared by the OGTR with input from the prescribed expert groups and this is made available for public consultation. Notice of the public consultation period is made in print media as well as on the website and through a mail-out to interested parties. Submissions made during this consultation are taken into account in the final RARMP and the public is then informed of the Regulators decision. The regulations provide that the OGTR must issue or refuse a licence in 170 days from the receipt of the application.

The *Gene Technology Act, 2000* also requires that the OGTR maintain a record of all GMO and GM product dealings and to provide this information to the public. In order to facilitate this, all applications for licenses are posted on the OGTR website when they are first received and again when public comment is sought.

## 3 Brazil

| **Summary of regulatory system for unconfined (commercial) release for domestic cultivation in Brazil** | |
|---|---|
| Regulatory Authority | National Technical Biosafety Commission (CTNBio) |
| Law | Law *Nº 11.105 of March 24th, 2005* |
| Regulations | Normative Resolution No. 05 of March 12, 2008 |
| Guidance | |

The environmental release of GE crops in Brazil is regulated under *Law Nº 11.105* of *March 24th, 2005*, which was passed after a protracted legal and political battle in Brazil that had resulted in a moratorium on the release of GE crops from 1998 until 2005. Law Nº 11.105 and Decree No. 5,591, of November 22, 2005 redefined the roles and responsibilities of the key regulatory authorities, the National Biosafety Council (CNBS) and the National Technical Biosafety Commission (CTNBio). CNBS in a council of 11 ministers responsible for "formulating and implementing the National Biosafety Policy".

[22] http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/raf-3/$FILE/raffinal3.pdf

[23] http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dirform-1/$FILE/dirform4.pdf

CTNBio, under the Ministry of Science and Technology, is a multi-disciplinary body of 54 members (27 full and 27 substitute members, all of who must have Ph.Ds) that "provides technical and assistance support to the Federal Government to formulate, update and implement the National Biosafety Policy for GMOs and their by-products, as well as establishes safety technical norms regarding the authorization of researchrelated activities and the commercial use of GMOs and their by-products, based on the evaluation of their zoo-phytosanitary, human health and environmental risk". From an operational standpoint, CTNBio is the key regulatory and risk assessment authority.

A series of eight Normative Resolutions have been passed since 2005[24]. Normative Resolution No. 05 of March 12, 2008 details rules for the commercial release of GMOs and their derivatives with Annex IV describing the information and data requirements for environmental risk assessment. Article 10(VIII) and Annex I address the requirement for the submission of a post-commercial release monitoring plan to CTNBio for its review and approval. The requirements for post-release monitoring were recently amended to provide case-specific flexibility, including the possibility of an exemption from monitoring,

## 4 Canada

| **Summary of regulatory system for unconfined (commercial) release for domestic cultivation in Canada** | |
|---|---|
| Regulatory Authority | Canadian Food Inspection Agency (CFIA) |
| Law | *Seeds Act* |
| Regulations | Seeds Regulations, Part V |
| Guidance | Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits |

The regulation of agricultural biotechnology products is coordinated between the Canadian Food Inspection Agency (CFIA), Health Canada, and Environment Canada. In all cases, these agencies have used existing acts to incorporate new or amend existing regulations. The CFIA is responsible for regulating the environmental release of plants with novel traits (PNTs), including transgenic plants, under the *Seeds Act.* PNTs are plant varieties/genotypes that are not considered substantially equivalent, in terms of their specific use and safety both for environment and for human health, to plants of the same species, having regard to weediness potential, gene flow, plant pest potential, impact on non-target organisms and impact on biodiversity. PNTs may be produced by conventional breeding, mutagenesis, or more commonly, by recombinant DNA techniques.

In 1996, the Canadian government amended the *Seeds Act* and its regulations with the promulgation of Part V, Release of Seed, which was further amended

[24] http://www.ctnbio.gov.br/index.php/content/view/12845.html

in 2000. These regulations prescribe the requirements for mandatory environmental and human health safety assessment prior to authorization for unconfined environmental release (commercial release). Guidelines detailing the information and data requirements for the environmental risk assessment of PNTs were published in 1994 as Regulatory Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits and revised in 2000 and 2004.

## 5 The European Union

| **Summary of regulatory system for unconfined (commercial) release for domestic cultivation in the European Union** | |
|---|---|
| Regulatory Authority | European Food Safety Authority |
| Regulation | Directive 2001/18/EC of the European Parliament and of the Council |
| Guidance | Guidance on the Environmental Risk Assessment of Genetically Modified Plants; Guidance on the Post-Market Environmental Monitoring (PMEM) of Genetically Modified Plants; Guidance Document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants Containing Stacked Transformation Events |

The European Union has a somewhat complicated governmental structure, with the central regulatory authority residing in the European Commission, but all legislative power resting in the national governments of the member states. Furthermore, final decision-making authority in the EU resides with the Ministerial Council, made up of ministers from the various member states, often under a qualified majority voting system. This allows political issues to enter into many decisions and has, in particular, been a problem for decisions related to products of agricultural biotechnology, specifically GE crops.

Directive 2001/18[25] describes the regulatory procedure that must be followed to obtain permission for the deliberate release into the environment of genetically modified organisms, including GE plants.

Additionally, it provides a common methodology to assess environmental risks on a case-by-case, common objectives for the monitoring of genetically modified organisms after their deliberate release or placing on the market, and a mechanism allowing the release of the genetically modified organisms to be modified, suspended or terminated where new information becomes available on the risks of such release. Supplemental information is provided in a series of very detailed and prescriptive guidance documents: Guidance on the Environmental Risk Assessment of Genetically Modified Plants[26]; Guidance on the Post- Market Environmental Monitoring (PMEM) of Genetically Modified Plants[27]; Guidance Document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants Containing Stacked Transformation Events[28]

[25] http://rod.eionet.europa.eu/instruments/559

[26] http://www.efsa.europa.eu/en/efsajournal/doc/1879.pdf

[27] http://www.efsa.europa.eu/en/efsajournal/doc/2316.pdf

[28] http://www.efsa.europa.eu/en/efsajournal/doc/512.pdf

## 6 United States

| Summary of regulatory system for unconfined (commercial) release for domestic cultivation in the US | |
|---|---|
| Regulatory Authority | Animal and Plant Health Inspection Service (APHIS), US Department of Agriculture (USDA)<br>US Environmental Protection Agency (USEPA) |
| Law | *Plant Protection Act; Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA) |
| Regulations | 7CFR340 - Introduction of organisms and products altered or produced through genetic engineering which are plant pests or which there is reason to believe are plant pests; 40CFR152 - Pesticide registration and classification procedures; 40CFR17- Procedures and requirements for plant-incorporated protectants; 40CFR172 – Experimental use permits. |
| Guidance | Canada-US Bilateral Agreement on Agricultural Biotechnology |

In 1993, USDA finalized a regulation under the *Federal Plant Protection Act* (formerly the *Federal Plant Pest Act)* that described a petition process for determining that particular plants would no longer be regulated and, therefore, could be commercially planted. A regulated article is defined as any organism which has been altered or produced through genetic engineering if the donor organism, (e.g., cauliflower mosaic virus 35S promoter), recipient organism, or vector or vector agent (e.g., *Agrobacterium tumefaciens* mediated transformation) belong to any genera or taxa designated as, or believed to be, a plant pest. The regulations are contained within 7 CFR (Code of Federal Regulations) Part 340, "Introduction of Organisms and Products Altered or Produced through Genetic Engineering which are Plant Pests or Which There is Reason to Believe are Plant Pests". Although APHIS' regulations for genetically engineered plants apply only to plant pests, the Agency's broad discretionary authority has provided them with sufficient latitude to consider most transgenic plants as a potential plant pest. Recently, however, APHIS released a notice confirming that a genetically-engineered, herbicide-tolerant Kentucky bluegrass that was developed by a single gene insertion without using any "plant pest components"[29]. As such, it does not fall within the definition of a regulated article under the *Plant Protection Act,* i.e., it is not a plant pest, is not made using plant pests, and consequently APHIS determined it had no reason to believe that it is a plant pest[30].

The USEPA is responsible for regulating pesticides in the United States, including pesticidal substances produced through biotechnology (e.g., Cry proteins, viral coat proteins). In 1994, the EPA published proposed regulations describing policies for pesticidal substances expressed in transgenic plants under FIFRA and the *Federal Food Drug and Cosmetics Act.* In 2001, this rule was finalized along with two others that clarify which "plant-incorporated protectants" (PIPs) are exempt from regulation. Under the final rules, most components of PIPs derived from genetic engineering will be subject to FIFRA and FFDCA requirements to ensure that federal safety standards are met.

[29] http://www.federalregister.gov/articles/2011/07/07/2011-17117/scotts-miracle-gro-co-regulatory-status-ofkentucky-bluegrass-genetically-engineered-for-herbicide

[30] http://www.aphis.usda.gov/brs/aphisdocs/scotts_kbg_q&a.pdf

# Annex II: Intergovernmental Organisations Developing Guidance for the Environmental Risk Assessment of GE Plants

## 1 Ad hoc Technical Expert Group on Risk Assessment and Risk Management

The Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management under the Cartagena Protocol on Biosafety met for the first time in April 2009 to discuss the development of guidance documents to further support countries in conducting risk assessments of living modified organisms (LMOs) in the context of the Cartagena Protocol[31]. The AHTEG has met three times to draft "Guidance on the Risk Assessment of LMOs"[32]. It has additionally established sub-working groups to develop guidance documents on specific aspects of risk assessment and risk management, namely:

- Roadmap for Risk Assessment
- Risk Assessment and Risk Management of Living Modified Crops with Resistance or Tolerance to Abiotic Stress
- Risk Assessment and Risk Management of Living Modified Mosquitoes
- Risk Assessment and Risk Management of LMOs with Stacked Genes or Traits
- Post-release Monitoring and Long-term Effects of LMOs Released into the Environment
- Risk Assessment of LM Trees

None of the guidance documents developed by the AHTEG and its sub-working groups have been finalized. Both the process used to develop these documents and the content of the documents themselves have been controversial, as evidenced by the comments submitted to the Secretariat to the Convention on Biological Diversity as part of a scientific review of the AHTEG's "Guidance on Risk Assessment of LMOs"[33] and a series of on-line discussions groups[34].

[31] The Cartagena Protocol addresses the safe transfer, handling, and use of living modified organisms (LMOs). It is the only international environmental agreement that is concerned exclusively with products of modern biotechnology and its terpretation and implementation have had a significant impact on biosafety regulation in developed and developing countries. The Cartagena Protocol entered into force on 11 September 2003 and has been ratified by 162 countries (as of January 26, 2012). The risk assessment of LMOs is specifically addressed in Article 15 and Annex III which sets out general principles, methodological steps, and points to consider in the conduct of risk assessment of LMOs. The text of the Cartagena Protocol can be viewed at http://bch.cbd.int/protocol/text/.

[32] The "Guidance on the Risk Assessment of LMOs" is essentially a compilation of the other draft guidance documents being developed by sub-working groups of the AHTEG. The latest version of the document, dated 13 January 2012, can be accessed from http://bch.cbd.int/onlineconferences/discussiongroups_ra.shtml.

[33] The original submissions from Parties, other governments and organizations can be viewed at http://bch.cbd.int online conferences /ra_guidance/review.shtml#download.

[34] The text of the various discussion groups convened under the auspices of the AHTEG can be viewed at http://bch.cbd.int/onlineconferences/discussiongroups_ra.shtml.

## 2 The Working Group on Harmonisation of Regulatory Oversight in Biotechnology[35]

The OECD's Working Group on Harmonisation of Regulatory Oversight in Biotechnology (the Working Group) deals with the environmental risk/ safety assessment of transgenic plants and other genetically engineered organisms. The work aims to ensure that the type of information used in biosafety assessment, as well as the methods to collect such information, are as similar as possible amongst countries. This improves mutual understanding and harmonised practice, which in turn, increases the efficiency of the risk/ safety assessment process and avoids duplication of effort, while reducing barriers to trade.

The participants to the Working Group are mainly officials who have responsibility for the environmental risk/safety assessment of products derived from modern biotechnology. Observer delegations and invited experts are also associated with the work, including: Argentina; the Russian Federation; FAO; UNEP; the Secretariat of the Convention on Biological Diversity (SCBD); and the Business and Industry Advisory Committee to OECD (BIAC), and the Center for Environmental Risk Assessment (CERA) of the ILSI Research Foundation. Participation of non-member economies, such as Brazil, China, India, Philippines and South Africa, has increased due to the rising use of biotechnology products together with the development of activities on tropical and sub-tropical species. Their participation is supported by the OECD's Global Forum on Biotechnology.

The publication of consensus and guidance documents continues to be a major output of the Working Group. These documents[36] constitute a set of practical tools for regulators and biosafety assessors dealing with new transgenic plant varieties and organisms, with respect to environmental safety. Forty-three Consensus Documents have been published, addressing a range of issues particularly the biology of crops, trees and micro-organisms, as well as selected traits that have been introduced in plants. The Working Group is in the process of developing a new guidance document "Environmental Considerations for the Risk/Safety Assessment for the Release of Transgenic Plants".

[35] Reproduced from http://www.oecd.org/dataoecd/21/12/48464394.pdf.

[36] These documents can be viewed at http://www.oecd.org/document/55/ 0,3746,en_2649_34385_2500215_1_1_1_1,00.html.